Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of diltiazem gel in reducing complications and pain of anorectal surgery in patients candidates for anorectal surgery

Protocol summary

Study aim

1. Comparison of the effectiveness of deltiazem and placebo gel on pain score after anorectal surgery

Design

The clinical trial consists of two groups of intervention and control. Candidates for anorectal surgery are randomly selected by blocking method. The study is a double-blind study on 144 patients and the data were collected with SPSS22 software.

Settings and conduct

This study is a double-blind randomized clinical trial. 144 patients who are candidates for anorectal surgery in Shahid Beheshti Hospital in Qom will be randomly divided into two groups. The groups will be selected in such a way that individuals will be assigned to the groups based on block randomization. The intervention group will receive diltiazem gel immediately after the operation and then every 8 to 24 hours. The actions are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria All anorectal surgery candidates who have given informed consent and Criteria for excluding clinical trial patient dissatisfaction - pregnant women - sensitivity to diltiazem gel.

Intervention groups

The intervention group is patients who are candidates for anorectal surgery who receive postoperative diltiazem gel and these patients are randomly selected and the effect of diltiazem gel on postoperative pain and postoperative complications on them is investigated. The control group of patients are candidates for anorectal surgery who receive placebo and are compared with the intervention group in terms of postoperative pain score.

Main outcome variables

pain score after anorectal surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120118008769N5**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **retrospective**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Seyed Jalal Eshagh Hosseini

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25171181

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of diltiazem gel in reducing complications and pain of anorectal surgery in patients candidates for anorectal surgery

Public title
Evaluating the Efficacy of Diltiazem Gel in Reducing the Complications and Pain in Anorectal Operations

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for anorectal surgery Informed consent
Exclusion criteria:
Pregnant women Sensitivity to diltiazem gel

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization The study was performed using block randomization. To do this, permutation blocks have been used. Data were analyzed with SPSS 22 software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The clinical trial is two-way blind. Participants in this trial and the main researcher They do not know the type of medicine the patient is taking (diltiazem gel, placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
Qom University of Medical Sciences, Shahid Lavasani St.
City
Qom
Province
Ghoum
Postal code
3713649373

Approval date
2021-03-14, 1399/12/24

Ethics committee reference number
IR.MUQ.REC.1400.008

Health conditions studied

1

Description of health condition studied
Anorectal surgery

ICD-10 code
K60.5

ICD-10 code description
Anorectal fistula

Primary outcomes

1

Description
Postoperative pain score

Timepoint
Immediately after surgery then every 8 hours to 24 hours

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group receiving 2% diltiazem gel from Sobhan Pharmaceutical Company, one applicator immediately after surgery and every eight hours for the first 24 hours after anorectal surgery

Category
Treatment - Drugs

2

Description
Control group: Placebo receiving group (placebo)

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Shahid Beheshti Hospital, Farabi Limited Surgery Center

Full name of responsible person
Seyed Jalal Eshaqh Hoseini

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Shahid Beheshti St., Ammar Yaser St.

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Qom University of Medical Science

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Foreign

Category of foreign source of funding
Sponsor: country of origin

Country of origin
IR

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Seyed Jalal eshaqh Hoseini

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available